K112035

JAN - 5 2012

510(K) SUMMARY of SAFETY AND EFFECTIVENESS

SPONSOR:

Volcano Corporation
2870 Kilgore Road.
Rancho Cordova, CA 95670

CONTACT/SUBMITTER:

Lisa M. Quaglia
Senior Director, Regulatory Affairs
Volcano Corporation
1 Fortune Drive
Billerica, MA 01821
Tel: (978) 439-3586

DATE OF SUBMISSION:

December 2, 2011

DEVICE:

Volcano Valet™ Micro Catheter

Trade Name: Valet™ Micro Catheter
Common Name: Catheter, Percutaneous
Classification: 21 CFR Part 870.1250
Class II Device

PREDICATE DEVICE:

Asahi Corsair Microcatheter (K083127)

DEVICE DESCRIPTION:

The Valet™ Micro Catheter is a support catheter comprised of a catheter shaft and hub. It is available in lengths 100, 123, 135, and 150 cm. The outer diameter is available in 2 sizes and is tapered from 2.3F to 1.8F and 4.0F to 3.5F. The device offers 45° and 60° angled tips as well as a straight tip.

INTENDED USE:

The Valet™ Micro Catheter is indicated for use as a conduit for the exchange/support of guidewires in the peripheral and coronary vasculatures. The Valet™ Micro Catheter is also indicated to infuse and deliver saline and contrast agents. The Valet™ Micro Catheter is not intended for use in the neurovasculature.

COMPARISON OF CHARACTERISTICS:

The proposed device is substantially equivalent to currently marketed device. Both devices are support catheters consisting of a catheter shaft and hub. The proposed Valet™ Micro Catheter is offered in four catheter shaft lengths whereas the predicate device is offered in two lengths. Additionally, the Valet™ Micro Catheter offers multiple inner lumen diameters while the predicate device offers a single inner lumen diameter. The indications for use is the same for both devices.

PERFORMANCE DATA:

Non-clinical device testing was conducted to confirm the performance of the device. Bench testing was conducted against known standards, product specification, or against the predicate device and evaluated the following:

- Dimensional Verification
- Leak Testing
- Leak Testing of Air into the Hub During Aspiration
- Catheter Bond Strength
- Flexibility and Kink Test
- Torque Strength Test
- Radiopacity
- Coating Adhesion
- Coating Integrity
- Particulate Evaluation
- Catheter Body Burst Pressure
- Contrast Media Flow Rate

Biocompatibility testing was conducted on the device and the following tests were successfully completed:

- Cytotoxicity
- Sensitization
- Intracutaneous
- Systemic Toxicity
- ASTM Hemolysis
- *In Vitro* Hemolysis
- C3a Complement Activation
- SC5-b Complement Activation
- Pyrogens
- Hemocompatibility
- *In vivo* Thromboresistence

Completion of these tests concluded the Valet™ Micro Catheter is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN - 5 2012

Volcano Corporation
c/o Ms. Lisa M. Quaglia
Senior Director, Regulatory Affairs
1 Fortune Drive
Billerica, MA 01821

Re: K112035
Trade/Device Name: Volcano Valet™ Micro Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: December 2, 2011
Received: December 5, 2011

Dear Ms. Quaglia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M L Kilcheman

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K112035

Device Name Valet™ Micro Catheter

Indications for Use The Valet™ Micro Catheter is indicated for use as a conduit for the exchange/support of guidewires in the peripheral and coronary vasculatures. The Valet™ Micro Catheter is also indicated to infuse and deliver saline and contrast agents. The Valet™ Micro Catheter is not intended for use in the neurovasculature.

Prescription Use ___X____ OR Over the Counter Use _____
(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

M A Kellen

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112035